BIOAVAILABLE CAROTENOID-CYCLODEXTRIN FORMULATIONS FOR SOFT-GELS AND OTHER ENCAPSULATION SYSTEMS

ABSTRACT OF THE DISCLOSURE

The present invention describes an improved commercial process for the production of carotenoid-cyclodextrin complexes and formulation of the complex for human ingestion. Complexation with cyclodextrins (*e.g.*, α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, or HP-β-cyclodextrin) significantly improves the uptake of carotenoids (*e.g.*, lycopene, lutein, or zeaxanthin) and their mixtures *in vitro*. The method for making such complexes includes forming a carotenoid/cyclodextrin complex; freezing drying said carotenoid/cyclodextrin complex; and blending said freeze-dried carotenoid/cyclodextrin complex with a mixture of lecithin and a vegetable oil or a vegetable oil suitable for soft gelatin capsules. The cyclodextrin/carotenoid complex can be formed in a molar ratio of between about 0.5:1.0 and 10:1. *In vivo*, in a human study, the lutein/γ-cyclodextrin complex formulated in lecithin-oil or oil showed a better absorption of lutein, as compared to the free lutein-oil formulation.